label failed to bear adequate directions for use, adequate warnings, and the names of the active ingredients.

On November 28, 1941, the United States attorney for the Southern District of West Virginia filed a libel against the above-named product at Charleston, W. Va., alleging that the article had been shipped in interstate commerce on or about October 15, 1941, by the Arner Co., Inc., from Buffalo, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that its label failed to bear (1) adequate directions for use; (2) adequate warnings against use by children where its use might be dangerous to health, and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users, since the labeling carried no warning that repeated daily administration would cause systemic deleterious effects and injurious gastro-intestinal disturbances; and (3) the common or usual name of each active ingredient.

On April 20, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

670. Misbranding of Special S. C. White Pills Rx2609. U. S. v. 96,200 Special S. C. White Pills Rx2609. Default decree of condemnation and destruction. (F. D. C. No. 6744. Sample No. 30492-E.)

On January 21, 1942, the United States attorney for the Eastern District of Michigan filed a libel against the above-named product at Detroit, Mich., alleging that it had been shipped on or about November 22, 1941, by Charles H. Dietz, Inc., from St. Louis, Mo.; and charging that it was misbranded. The article was labeled in part: "Special S. C. White Pills Rx2609. Each pill contains—Aloes—¾ gr. Ferrous Sulphate—1¼ gr. Oil Pennyroyal—¼ min."

It was alleged to be misbranded (1) in that the label did not bear adequate directions for use; and (2) in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health since the label failed to bear a warning that it should not be taken when nausea, vomiting, abdominal pains, or other symptoms of appendicitis are present; and against unsafe dosage or duration of administration since the labeling failed to bear a warning that frequent or continued use might result in dependence on a laxative.

On March 24, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

671. Misbranding of Sterile Solution Formula No. 3, Rx Formula No. 8, and S. G. M. a. (Oral). U. S. v. 8 Vials of Sterile Solution Formula No. 3, 12 Boxes of Rx Formula No. 8, and 4 Bottles of S. G. M. a. (Oral). Default decree of condemnation and destruction. (F. D. C. No. 3911. Sample Nos. 50191-E, 50195-E, 50196-E.)

The labeling of the Sterile Solution Formula No. 3 and S. G. M. a (Oral) failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users and failed to bear the common or usual names of the active ingredients including the amount of strychnine in the former and of thyroid in the latter. The labeling of all three products failed to comply with certain other labeling requirements, as indicated hereinafter.

On February 4, 1941, the United States attorney for the Eastern District of Virginia filed a libel against the above-named products at Richmond, Va., alleging that they had been shipped in interstate commerce on or about December 31, 1940, by The Samaritan Treatment from Chicago, Ill.; and charging that they were misbranded.

Analysis of a sample of the Sterile Solution Formula No. 3 showed that it contained a solution of strychnine, emetine, ephedrine, pilocarpine, and sparteine. It was alleged to be misbranded (1) in that the label failed to bear adequate directions for use; (2) in that the label failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users; and (3) in that the label failed to bear the common or usual name of each of the active ingredients, including the amount of strychnine that it contained.

Analysis of a sample of Rx Formula No. 8 showed that the capsules each contained approximately 0.6 gram of a powder composed chiefly of iron and ammonium citrate. They were alleged to be misbranded in that they did not bear a label containing the name and place of business of the manufacturer, packer, or distributor; in that they did not bear a label containing a statement of the quantity of contents of the package; in that the label failed to bear the common

or usual name of the drug; and in that the label failed to bear the common or usual name of each active ingredient contained therein.

Analysis of a sample of the S. G. M. [illegible] (Oral) showed that it consisted of capsules containing animal materials including 0.16 grain of thyroid per capsule. It was alleged to be misbranded in that its labeling failed to bear adequate directions for use; in that its labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users; in that its package failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; in that its package failed to bear a label containing a statement of the quantity of the contents; in that the label failed to bear the common or usual name of the article; and in that the label failed to bear the common or usual name of each active ingredient, including the quantity of thyroid that it contained.

On January 7, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

672. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 94 Dozen Packages of Zerbst's Capsules. Default decree of destruction. (F. D. C. No. 6572. Sample No. 73122–E.)

This product contained acetanilid, aloin, and a resin such as podophyllin. In addition to failure to bear adequate directions and warnings on the label, it contained approximately 20 percent more acetanilid than the amount stated on the label.

On December 24, 1941, the United States attorney for the Western District of Missouri filed a libel against 94 dozen packages of Zerbst's Capsules at Kansas City, Mo., alleging that the article had been shipped on or about November 15, 1941, by J. Walker Burns & Co. from Chicago, Ill.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, (label) "Each Capsule contains as active ingredients, Acetanilid 1 Grain," since it contained materially more than 1 grain of acetanilid.

It was alleged to be misbranded: (1) In that the directions for use, "Adults—To allay the discomfort in breaking up a common head cold, simple headache or neuralgia, take one capsule every half hour until three are taken, then one capsule in two or three hours until three more capsules are taken. Children—12 years old, one capsule, repeated in three hours," were inappropriate for an article of its composition and were therefore inadequate. (2) In that the label failed to bear adequate warnings against its use by children or in those pathological conditions where its use might be dangerous to health and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users, since there was no warning against its use by children, against use in the presence of the symptoms of appendicitis, nor with reference to the deleterious effects of acetanilid in causing serious blood disturbances, or that frequent or continued use might result in dependence upon the drug.

On February 13, 1942, no claimant having appeared, judgment was entered ordering that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS[2]

673. Adulteration of chloroform. U. S. v. City Chemical Corporation and Max Wolpert. Plea of guilty. Corporation and Max Wolpert both fined $100. (F. D. C. No. 6404. Sample Nos. 47480–E, 50848–E.)

This product differed from the pharmacopoeial standard because of the presence of excessive carbonizable substances in both lots and of chlorinated decomposition products in one.

On February 18, 1942, the United States attorney for the District of New Jersey filed an information against the City Chemical Corporation, Newark, N J., and Max Wolpert, an officer of said corporation, alleging shipment on or about May 27, 1941, from the State of New Jersey into the States of Illinois and Maryland, of a quantity of chloroform that was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its quality or purity fell below the standard set forth in

[2] See also Nos. 656, 657, 668, and 672.